

### **REMARKS**

The Final Office Action mailed February 4, 2010 has been received and reviewed. Claims 32-52 are pending in the subject application. All pending claims stand rejected. Specifically, claims 32-40 and 49-52 stand rejected under 35 U.S.C. § 101, while claims 32-48 stand rejected under 35 U.S.C. § 103(a). Accordingly, claims 32, 34, 36, 41, 49, and 50 are amended as set forth herein. As such, upon entry of the proposed amendments, claims 32-52 will remain pending. It is submitted that no new matter has been added by way of the present amendments. Reconsideration of the subject application is respectfully requested in view of the proposed amendments and the following remarks..

### **Objections**

Claims 32, 34, 41, and 49 are objected to for the informality of stating “one family member of the person within the mode of inheritance,” which the Office contends to be awkward. In response, as more fully discussed below, each of these claims is amended to describe a traversal pattern governed by the mode of inheritance associated with a particular gene. Support for this amendment may be found in the Specification, for example, at paragraphs [0050] - [0055] and [0065].

### **Rejections based on 35 U.S.C. § 101**

Claims 32-40 and 49-52 were rejected under 35 U.S.C. 101 for being directed to non-statutory subject matter.

Initially, independent claims 32 and 49 are amended to include the step of “*utilizing the server* to identify at least one family member related to the person within a traversal pattern the person’s ancestors.” Because claims 32 and 49 recite a series of steps or

acts to be performed, these claims may be considered a process, which is one of the four statutory categories of invention provided by 35 U.S.C. § 101.

However, a proper § 101 process must (1) be tied to another statutory class, such as a particular apparatus, or (2) transform underlying subject matter, such as an article of manufacture, to a different state or thing.<sup>1</sup> As amended, independent claims 32 and 49 recite a server (e.g., computer, device, machine, or other physical article) that performs a logical step of the process. Accordingly, the use of the specific machine (i.e., server) to perform a process imposes meaningful limits on a scope of the claim, and imparts patent-eligibility.<sup>2</sup> Further, the involvement of the specific machine in the claimed process is not merely insignificant extra-solution activity, but serves to support the execution of the process.

As such, it is respectfully submitted that amended claims 32 and 49 are directed toward statutory subject matter. Further, each of claims 33-40 and 50-52 are believed to be in condition for allowance based, in part, upon their dependency from independent claims 32 and 49, respectively, and such favorable action is respectfully requested.<sup>3</sup>

Further, claims 36 and 50 are rejected for embodying instructions upon “computer readable media,” which the Office deems to include communication media (e.g., carrier waves) that fall outside the enumerated statutory subject matter of § 101. Accordingly, claims 36 and 50 have been amended herein to recite, in part, “computer storage media.” Upon amendment, it is asserted that claims 36 and 50 are limited to tangible embodiments. “When functional descriptive material is recorded on some computer-readable medium, it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since the use of

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<sup>1</sup> *Ex parte Bilski*, No. 2002-2257, 2006 WL 4080055, at \*10.

<sup>2</sup> *Id.*, at \*24.

<sup>3</sup> *See* 37 C.F.R. § 1.75(c) (2006).

technology permits the function of the descriptive material to be realized.”<sup>4</sup> As such, these claims relate to media encoded with a data structure that defines structural and functional interrelationships between the data structure of the computer software and hardware components. This permits the data structure’s functionality to be realized. Because claims 36 and 50 are now directed to computer-executable instructions embedded on “computer storage media” that stores a data structure, the claims constitute physical articles that fall within the statutory classes. Accordingly, withdrawal of the 35 U.S.C. § 101 rejections to dependent claims 36 and 50 is respectfully requested.

### **Rejections based on 35 U.S.C. § 103**

#### **A.) Applicable Authority**

The teachings or suggestions to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant’s disclosure.<sup>5</sup> To establish a *prima facie* case of obviousness, all the claim limitations must be taught by the prior art.<sup>6</sup> When determining whether a claim limitation is taught, “All words in a claim must be considered in judging the patentability of that claim against the prior art.”<sup>7</sup> Further, in establishing a *prima facie* case of obviousness, the initial burden is placed on the Examiner: “To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must

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<sup>4</sup> MPEP § 2106.01. *See, In re Lowry*, 32 F.3d 1579, 1583-84 (Fed. Cir. 1994) (discussing patentable weight of data structure stored on a computer readable medium that increases computer efficiency); *see also, In re Warmerdam*, 33 F.3d 1354, 1360-61 (discussing patentable weight of data structure limitations in the context of a statutory claim to a data structure stored on a computer readable medium that increases computer efficiency).

<sup>5</sup> *See* MPEP § 2143; *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

<sup>6</sup> MPEP § 2143.03; *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974).

<sup>7</sup> MPEP § 2143.03; *In re Wilson*, 57 C.C.P.A. 1029, 1032 (1970).

present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.”<sup>8</sup>

B.) Obviousness Rejection

Claims 32-40 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,112,182 to Akers et al. (hereinafter Akers) in view of WO 2001/01218 to Denton et al. (hereinafter Denton) in view of *Automatic Computation of Genetic Risk*, 1043-0989/94, IEEE, 1994 to Pathak et al. (hereinafter Pathak). As the Akers, Denton, and Pathak references, whether taken alone or in combination, fail to teach or suggest all of the limitations of the rejected independent claim 32 as amended herein, Applicants respectfully traverse this rejection, as hereinafter set forth.

Independent claim 32 is directed to a computer-implemented method for determining and presenting the likelihood a person has a mutated form of a gene. As amended herein, the method comprises the following steps:

- “in response to the electronic order, obtaining the mode of inheritance for the gene if the person does not have one or more genetic test results for the gene, wherein *the mode of inheritance is selected based upon the gene associated with the at least one clinical agent;*”
- “*utilizing the server to identify at least one family member related to the person within a traversal pattern the person’s ancestors, wherein the traversal pattern is specified by the selected mode of inheritance of the gene;*”
- without solicitation from a clinician, querying a second database to determine whether at least one identified family member of the person within the traversal pattern has one or more genetic test results for the gene” (emphasis added).

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<sup>8</sup> *Ex parte Clapp*, 227 USPQ 972, 972 (Bd. Pat. App. & Inter. 1985); *see also* MPEP §706.02(j) and §2142.

In this way, the mode of inheritance (e.g., mitochondrial mode, autosomal mode, X linked mode, and Y linked mode)<sup>9</sup> is selected based on the gene and utilized to determine which members of the person's family to examine based on the traversal pattern of laid out by the mode of inheritance of the gene.

The Office indicates at page 2 of the Office Action, mailed Feb. 4, 2010, that the phrase "one family member of the person within the mode of inheritance" is interpreted as any family member genetically related to the person. However, the clarifying language above, which is added to claim 32, requires the family member used for examination to have, at least, the characteristic of being included within the "traversal pattern . . . specified by the selected mode of inheritance of the gene."

The Office concedes that neither the Akers reference nor the Denton reference teach the steps of generating a likelihood that the person (e.g., patient) has a mutation. Yet, the Office relies on Pathak to teach using a set of rules to identify a route of inheritance of the mutation based on familial relationships as well as to utilize the loci information to calculate a probability of an allele's presence. However, Pathak does not describe (a) "obtaining the mode of inheritance for the gene . . . [that] is selected based upon the gene associated with the at least one clinical agent, (b) "identify[ing] at least one family member related to the person within a traversal pattern the person's ancestors, wherein the traversal pattern is specified by the selected mode of inheritance of the gene, and (c) "determin[ing] whether at least one identified family member of the person within the traversal pattern has one or more genetic test results for the gene." Instead, Pathak identifies via testing a set of allele already known to be present within a child and at least one parent and compares the identified alleles to trace the allele's manner of

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<sup>9</sup> See Specification at FIG. 3, reference numeral 60, and at ¶¶ [0051] – [0054].

inheritance.<sup>10</sup> As such, Pathak requires knowledge of the genetic information of various relatives prior to identifying a flow of an allele, while amended claim 32 recites identifying the appropriate traversal pattern based on a mode of inheritance known for the gene identified as being associated with the medication ordered for the person. Advantageously, the proper family members are identified as candidates for examination without performing any initial genetic testing. Therefore, the cited references do not teach or suggest each and every element of claim independent claim 32, as amended herein. Accordingly, Applicants respectfully request withdrawal of the § 103(a) rejection.

Claims 41-48 were rejected under 35 U.S.C. 103(a) as being unpatentable over Akers, Denton, and Pathak, in view of Wijker, et al. (Hum. Mol. Gen., Vol. 5, No.1, p. 151-154, 1996), and in view of Lathrop, et al. (PNAS, Vol. 81, p. 3443-3446, 1984). Independent claim 41 is amended in a similar fashion to claim 32 and, for at least this reason, is not unpatentable in view of Akers, Denton, and Pathak. Further, the Office does not cite the Wijker and Lathrop references for teaching the steps (a) – (c) above. Therefore, Applicants respectfully request withdrawal of the § 103(a) rejection.

Claims 49-53 were rejected under 35 U.S.C. 103(a) as being unpatentable over Akers, Denton, and Pathak, in view of Pratt, et al. (AM J. Hum. Genet., Vol. 66, p. 1153-1157, 2000). Independent claim 49 is amended in a similar fashion to claim 32 and, for at least this reason, is not unpatentable in view of Akers, Denton, and Pathak. Further, the Office does not cite the Pratt reference for teaching the steps (a) – (c) above. Therefore, Applicants respectfully request withdrawal of the § 103(a) rejection.

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<sup>10</sup> *Pathak* at pg. 166, cols. 1 and 2.

### **CONCLUSION**

For at least the reasons stated above, claims 32-52 are now in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned – 816-474-6550 or btabor@shb.com (such communication via email is herein expressly granted) – to resolve the same.

Fees for a Two-Month Extension of Time and Request for Continued Examination are submitted herewith. It is believed that no additional fee is due, however, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112, referencing Attorney Docket CRNI.107055.

Respectfully submitted,

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